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AMERICAN COLLEGE OF SURGEONS
Inspiring Quality: Highest Standards, Better Outcomes
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SPECIAL SESSION ON FIREARM INJURY PREVENTION: TRANSFORMING SURVEY RESULTS INTO ACTION

Monday's Firearm Injury Prevention session—one of three Special Sessions at Clinical Congress 2016 with a focus on timely issues—summarized the results of the American College of Surgeons (ACS) Committee on Trauma (COT) survey, revealing participants' views on a variety of firearm injury-related topics. The session was moderated by Ronald C. Stewart, MD, FACS, Chair of the ACS COT.

"The real issue is not firearms, it is freedom," said Dr. Stewart, who called for attendees to "bridge the perceived chasm" between both sides of the issue by "developing a consensus on how to reduce needless injuries without limiting the personal freedom of legitimate, responsible firearms owners."

The session began with a presentation examining firearm injury epidemiology at U.S. trauma centers by Peter A. Burke, MD, FACS. "Using

National Trauma Data Bank data, the most common trauma injuries we see are due to falls (44 percent), followed by traffic-related injuries (33.5 percent). Firearm injuries represent only 4 percent of the injuries we see in trauma centers," Dr. Burke said.

"However, when it comes to mortality, firearm injuries are almost equal to motor vehicle collisions and surpass falls," added Dr. Burke, citing data from the Centers for Disease Control and Prevention (CDC) National Center for Health Statistics. Firearm deaths in adults (ages 15 and older) are largely a result of suicides, followed by homicides, with a much lower level of unintentional firearm deaths, he said.

On the other hand, for children (age 14 and younger) the rate of intentional injury has been steadily declining, according to Barbara A. Gaines, MD, FACS, while gun-related homicide deaths, although decreased from the peak incidence in the 1990s, have been relatively constant. Suicide deaths are increasing in this age group. "Firearm-related deaths are the second-leading cause of death in children," Dr. Gaines said.

Brendan T. Campbell, MD, MPH, FACS, described the development of the ACS COT Firearms Injury Prevention Survey, which featured 32 questions and was submitted to 254 COT members with a response rate of 93 percent. "Our charge…was to go at this with equipoise," said Dr. Campbell, noting that the survey was designed to uncover "ACS COT member attitudes about firearm ownership, freedom, responsibility, and public policy."

FIREARM SURVEY continued on page 8

Annual Business Meeting of Members convenes Wednesday

The Annual Business Meeting of the Members of the American College of Surgeons (ACS) will take place 4:15–5:15 pm Wednesday at the Walter E. Washington Convention Center, 145. At this meeting, ACS members will elect Officers, Regents, and Governors. In addition, the following officials will present their annual reports: the Chair of the Board of Regents, Chair of the Board of Governors, ACS Executive Director, and Chair of the ACS Professional Association's political action committee (ACSPA-*Surgeons*PAC). A number of awards also will be presented. For the complete agenda, see page 34 of the Clinical Congress Program Book.

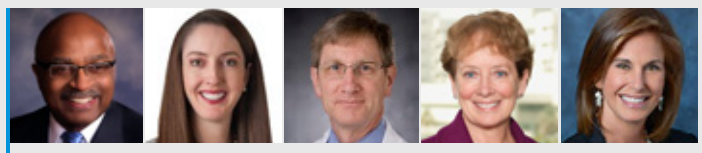
All members are respectfully encouraged to attend.

Three ACS Fellows elected, two inducted to NAM

Three Fellows of the American College of Surgeons (ACS) were elected to the National Academy of Medicine (NAM) Monday during the academy's annual meeting. These Fellows are as follows:

- ACS Past-President L. D. Britt, MD, MPH, DSc(Hon), FACS, FCCM, FRCSEng(Hon), FRCSEd(Hon), FWACS(Hon), FRCSI(Hon), FCS(SA)(Hon), FRCS(Glasg)(Hon), Henry Ford Professor and Edward J. Brickhouse Chair, department of surgery, Eastern Virginia Medical School, Norfolk
- Melina Rae Kibbe, MD, FACS, the Zach D. Owens Distinguished Professor and chair, department of surgery, University of North Carolina School of Medicine, Chapel Hill
- Allan Douglas Kirk, MD, PhD, FACS, David C. Sabiston, Jr., Professor and chair, department of surgery, Duke University School of Medicine, Durham, NC

Drs. Britt, Kibbe, and Kirk were among the 70 regular members and nine international members inducted into NAM. Election to the academy is considered one of the highest honors in the fields of health and medicine and recognizes individuals who have demonstrated outstanding professional achievement and commitment to service. New members are elected by current active members through a selective process that recognizes individuals who have made major contributions to the advancement of the medical sciences, health care, and public health.



Left to right: **L. D. Britt,** MD, MPH, DSc(Hon), FACS; **Melina Rae Kibbe,** MD, FACS; **Allan Douglas Kirk,** MD, PhD, FACS; **Julie A. Freischlag,** MD, FACS; and **Beth Y. Karlan,** MD, FACS

"These newly elected members are outstanding professionals who care deeply about advancing health and health care in the U.S. and globally," said National Academy of Medicine President Victor J. Dzau. "Their expertise will help our organization address pressing health challenges and improve health, science, and medicine for the benefit of us all. It is my privilege to welcome these accomplished individuals to the National Academy of Medicine."

In addition, two ACS Fellows who were elected to NAM last year were officially inducted this week: Julie A. Freischlag, MD, FACS, Past-Chair of the Board of Regents, vice-chancellor for human health sciences, and dean of the University of California Davis School of Medicine; and Beth Y. Karlan, MD, FACS, professor, obstetrics and gynecology, director, Women's Cancer Program, Samuel Oschin Comprehensive Cancer Institute, and director, division of gynecologic oncology, Cedars-Sinai Medical Center, Los Angeles, CA.

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EXPERTS DISCUSS MEDICARE PAYMENT STRATEGIES DURING TOWN HALL MEETING

The staff of the American College of Surgeons (ACS) is in the process of reviewing the more than 2,200-page final rule on the new Medicare physician payment system released Friday by the Centers for Medicare & Medicaid Services (CMS). However, the initial review reveals that the agency is providing increased flexibility compared with the proposed rule to promote physicians' participation success in the Quality Payment Program (QPP), according to speakers at a Town Hall meeting on Tuesday at Clinical Congress 2016.

James C. Denneny, MD, FACS, a member of the ACS Board of Regents, and Frank G. Opelka, MD, FACS, Medical Director, Quality and Health Policy, ACS Division of Advocacy and Health Policy, provided an overview of the pathways for surgeons to participate in the new payment program created by the Medicare Access and CHIP (Children's Health Insurance Program) Reauthorization Act (MACRA) of 2015. MACRA repealed the broken sustainable growth rate formula previously used to calculate Medicare physician payments, and created the QPP. CMS has created two pathways to participate in the QPP: the Merit-based Incentive Payment System (MIPS) and Alternative Payment Models (APMs).

MIPS was the primary focus of Tuesday's Town Hall, as the vast majority of surgeons, and all physicians, initially will participate in the QPP through this pathway. Surgeons who participate in MIPS could achieve a +/- 4 percent bonus in 2019 based on their participation in 2017. Payments under the QPP, whether participating through MIPS or APMs, will begin in 2019 based on participation in 2017.

> "If you take any message out of this Town Hall, it is to figure out your MIPS strategy."
>
> -Frank G. Opelka, MD, FACS

CMS initially proposed four component scores for MIPS: Quality, 50 percent; Advancing Care Information (ACI), 25 percent; Clinical Practice Improvement Activities (CPIA), 15 percent; and Resource Use, 10 percent. However, CMS has removed the Resource Use component in the first year and the Quality component will increase to 60 percent.

"CMS is calling 2017 a transition year," Dr. Denneny said. "Originally we were going to have to begin reporting on January 1 for a full year. However, CMS put three MIPS options in the final rule, or physicians may join an advanced APM."

CMS will now allow reporting for any consecutive 90-day period in 2017. Physicians may report on one Quality measure, one CPIA measure, or report the required ACI measures, and get credit. "That credit will not necessarily be a positive adjustment, but it will keep you from getting a negative adjustment," Dr. Denneny said.

"For CMS, MIPS is budget neutral," Dr. Opelka said. "Savings from cuts to providers falling below the low threshold CMS sets will be redistributed to those above the threshold. Although the threshold is set extremely low, CMS still expects it to yield about $190 million. The agency will roll those funds into the reward side, which could result in the neighborhood of a 3 percent bump to top performers."

By statute, there's another $500 million that will be distributed to outstanding providers, who may see an additional bonus of 9 to 10 percent.

"If you take any message out of this Town Hall, it is to figure out your MIPS strategy," Dr. Opelka urged attendees.

Some surgeons will be eligible to participate in APMs or advanced APMs. There are many ways to participate, one being participation in an accountable care organization (ACO). Participants in an upside and downside ACO can get credit for being in an advanced APM. There is also an opportunity to get credit through participation in bundled payment initiatives. Several surgical specialties are already participating in bundled payment initiatives, including cardiac surgery and orthopaedic surgery.

"The ACS is working on other initiatives with CMS and Brandeis University to build episodes of care, which take a condition such as cancer or a procedure such as a colectomy and define periods of time and all of the events of care within that time, and basically set a target price on that," Dr. Opelka said. "If you come in under the target price, you are rewarded. If you are over the target price, you go with risk, and you owe a percentage of that back. These episodes of care likely will not be ready until January 2018. For now, I would focus on MIPS."

More information about the QPP is available at *facs.org/qpp*, or at the QPP booth in the Grand Lobby of the Walter E. Washington Convention Center.

Universal access to surgical care addressed during panel session

The importance of universal access to surgical care has assumed increased significance in recent years, with the American College of Surgeons (ACS) and *The Lancet*, among other organizations, devoting considerable time and effort to exploring this issue. During the Monday Panel Session, Universal Access to Surgery: The Good, the Bad, and the Ugly, moderated by Charles V. Coren, MD, FACS, surgeons addressed this challenge from various perspectives.

Co-moderator Jamal J. Hoballah, MD, FACS, introduced the first speaker, O. N. M. Panton, MB, BS, FACS, FRCSC, head, University of British Columbia Division of General Surgery, who discussed access to care in Canada. Dr. Panton spoke on significant costs associated with Canadian health care, which is publically funded. Spending recently topped $200 billion per year—however, "in spite of high spending, access to health care is a real problem with respect to primary and long-term care," Dr. Panton said.

Since 2004, the Canadian provinces have recorded data, including patient wait times, to better understand the issue, which has led to "major improvements over the past decade," Dr. Panton said. He discussed different funding structures, problems with physician and patient accountability, and possible fixes to some of the persistent issues with access to surgical care, including embracing technology, a focus on patient wellness, and "funds that follow the patients, not the facilities," he said.

Kamal M. F. Itani, MD, FACS, chief of surgery, Veterans Affairs (VA) Boston Health Care System, MA, discussed patient access to surgical care in the VA system. He spoke of the Veterans Health Affairs scandal of 2014 in Phoenix, AZ, where some staff were falsifying data about patients being seen within the 14-day guideline set by the administration. "All that we heard, and that we still hear, is how bad access is to the VA," he said. "But within every challenge is an opportunity."

Dr. Itani noted that the VA health system is the largest in the U.S., and that working in the VA is different from working in the private sector because of the complete range of services offered to patients. The 2014 scandal has led to an infusion of funding from Congress, which has been used to hire more staff and upgrade facilities, all of which has increased overall access to surgical care in the VA population, he said.

Daniel D. Klaristenfeld, MD, FACS, colorectal surgeon, Southern California Permanente Medical Group, discussed access to surgery within the Kaiser Permanente health system, specifically in San Diego, CA. He explained that the system, which is lauded for quality by both physicians and patients, operates at a high level by carefully monitoring what happens in the operating rooms.

"We have a scorecard for each area that looks at adverse events, never events, start-up time for elective, urgent, and emergent operations, and we look at how long patients are waiting before they have their surgery," Dr. Klaristenfeld said.

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Challenges for the Second Century

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***Clinical Congress Daily Highlights* recap scientific sessions**

Don't miss the twice-daily Clinical Congress Daily Highlights e-Newsletter! Today's stories include pediatric neurologic anesthetic risks, an update on the American College of Surgeons' military partnership, cancer immunotherapy, and appropriate treatment for appendicitis.

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@AmCollSurgeons @WomenSurgeons learned how to #StoptheBleed Great initiative! #ACSCC16 #AWS2016
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"70% of what I do today I was not taught in residency." -Valerie Rusch. Excited for an evolving path in surgery! #ACSCC16
@gfchao

'We are always guests in a country when we respond to int'l disasters, we adjust our care to fit their needs, culture.' Dr. Briggs #ACSCC16
@annajdare

#ACSCC16 Orlo Clark: 'You have to love what you do. You may not like what you do every day, but you have to love it.'
@SanzianaR

Some of the laparoscopic displays vendors have set up st #ACSCC16 are *amazing*---they look almost as good as open surgery!
@jonessurgery

Such an honour and a privilege to present at this prestigious meeting. #ACSCC16
@MsY_Hassen

In 1991 my father and mentor introduced me to Dr Feliciano. Since then he has been my surgical "godfather" #ACSCC16 #humble #mentee
@pferrada1

Thrilled to join the world's preeminent surgical leaders as a Fellow of the **American College of Surgeons #ACSCC16 #cc16selfie #FACS**
@LaraDevganMD

Alexa Canady explains that community is important for surgical trainees to succeed including working with others like them #ACSCC16
@WomenSurgeons

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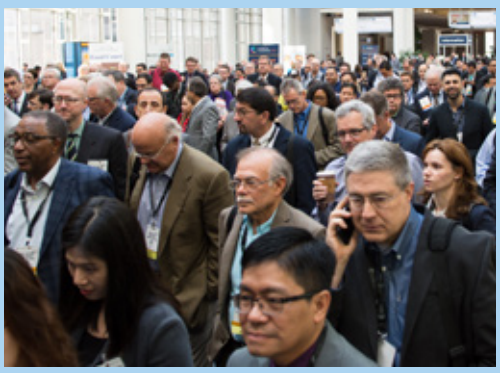


As of Tuesday afternoon, total registration for Clinical Congress 2016 was 12,805; 8,737 were physicians, and the rest were exhibitors, guests, spouses, and convention personnel.

ACS FOUNDATION APPLAUDS ANOTHER SUCCESSFUL PHILANTHROPIC YEAR

On Monday, members of the American College of Surgeons (ACS) Fellowship Leadership Society gathered in the Liberty Ballroom of the Marriott Marquis Washington DC, for the 28th Annual Donor Recognition Luncheon. Shane Hollett, Executive Director of the ACS Foundation, welcomed approximately 200 attendees and thanked them for their support of the charitable and educational work of the College.

The Foundation continues to prove itself "strong in its mission," Mr. Hollett said.

Amilu Stewart, MD, FACS, Chair of the ACS Foundation, recognized several major donors, as well as the recipient of the 2016 Distinguished Philanthropist Award, Mary H. McGrath, MD, FACS, professor of surgery, division of plastic surgery, University of California, San Francisco (UCSF). In 2011, Dr. McGrath was the recipient of the College's highest honor, the Distinguished Service Award. In honoring Dr. McGrath, an ACS donor since 1994, Dr. Stewart reflected on her commitment to the College not only as a donor but also as one who has served the larger philanthropic community, dedicated her time to ACS volunteerism, and committed herself to quality surgical patient care throughout her career.

Dr. McGrath has made many clinical and academic contributions to plastic surgery, especially in the areas of breast and hand surgery, wound healing, new technology, and workforce issues. She has held her current position at UCSF since 2003, has held many national positions in plastic surgery, and is currently president-elect of the American Association of Plastic Surgeons. She served on the ACS Board of Governors Executive Committee and as a Governor-at-Large representing the District of Columbia, and is a member of the ACS Foundation Board.

Mary H. McGrath, MD, FACS

Surgeons are fortunate individuals who want to say thank you, Dr. McGrath said in accepting the award. "We realize that surgical principles and ideals will carry on after us. The College takes on the issues, one at a time, in a collective voice that is informed by the people in this room," she said.

Strong philanthropic year

Dr. Stewart reported that the ACS Foundation provided the College with more than $3 million in support over the past year, and noted that donations to the foundation support the College's sustaining fund, quality patient care, professional education, scholarships, and special initiatives. It is the support of Dr. McGrath and other surgeons—mentors and donors—that ensures that the next generation will continue the "legacy of healing patients and transforming lives," Dr. Stewart said.

"You are saving lives through support for surgeons and research on optimal patient care, in the U.S. and around the globe," Dr. Stewart said to the luncheon attendees. "The care of the surgical patient and safeguarding of the profession are the driving forces of all that the ACS does each day. Thank you for being a part of this important work."

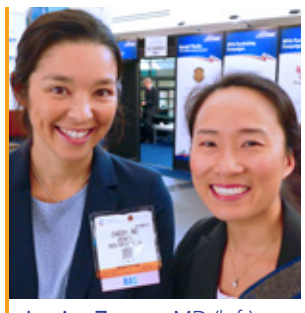
Mr. Hollett introduced Chad A. Perlyn, MD, FACS, an attending plastic surgeon, division of plastic and reconstructive surgery, Nicklaus Children's Hospital, and chief, division of plastic surgery, Herbert Wertheim College of Medicine, Florida International University, Miami. "As a pediatric plastic surgeon, his practice is dedicated solely to caring for children and young adults with congenital or acquired anomalies and injuries," Mr. Hollett said.

Dr. Perlyn was the recipient in 2003 of the ACS Resident Research Scholarship, which allowed him to spend three years at the University of Oxford in England, where he earned a doctorate degree in craniofacial molecular biology. "The most important part of my job is taking care of the patients, but the other part is the mentoring," Dr. Perlyn said. "Had I not gotten that grant from the ACS, my life would be extremely different. This would not have happened without you all."

"Through your donations," Mr. Hollett told the luncheon gathering, "we help brilliant scientists like Dr. Perlyn perform miracles on children."

QUESTION OF THE DAY

How will you describe Clinical Congress to your colleagues when you get back home?



Jessica Zagory, MD (left), Resident Member, New Orleans, LA
Minna Wieck, MD, Resident Member, Portland, OR

"We would describe it as surgical nerd camp: fun, chaotic, and educational. You come back and see everyone you've seen from previous years and everyone here is really excited about what they're doing. But it is really nerdy—it's where we feel most at home."

Steven N. Burger, MD, FACS, ACS Governor, Scarsdale, NY

"I'm here as an ACS Governor to do the business of the College. I would tell others that the ACS is the ultimate parent institution and it carries forward the true meaning of surgery to and for its members through education, advocacy, and policy throughout the year, and at Congress."

Ndidi Nelly Azikiwe, MD, FACS, Raleigh, NC

"Clinical Congress is certainly something I would suggest everybody attend at least once, if not more, in their career. It is a way to affirm that we are practicing in an acceptable way and that we are on track to gain the knowledge that all practicing surgeons should have."

Lucian Panait, MD, FACS, Brigantine, NJ

"It is the best meeting of the year and the one with the most informative sessions. Definitely an excellent venue for seeing old friends and making new connections."

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Panelists encourage surgeons to become more culturally dexterous

Panelists at a Tuesday morning session titled Understanding Diversity, Navigating Bias noted that patient-physician communication and health care outcomes often are negatively affected by implicit biases and encouraged attendees to become not just more culturally competent, but more culturally dexterous.

Session moderator Kathleen A. LaVorgna, MD, FACS, director, trauma service, and assistant chairman of the department of surgery, Norwalk Hospital, CT, and a member of the American College of Surgeons (ACS) Committee on Diversity Issues, noted that although surgical education and training programs are making a greater effort to encourage discussion of cultural differences, they may not be addressing the biases that affect the level and quality of care that patients receive.

Co-moderator Shubhada M. Dhage, MD, FACS, who also serves on the Committee on Diversity Issues, said a considerable amount of evidence has emerged in recent decades to indicate that although "we all want to provide patient-centered care," significant disparities in access to care in the U.S. persist, largely due to cultural biases.

Dr. Dhage, assistant professor of surgery and director, diversity in cancer research, New York University Langone Medical Center, NY, defined the difference between implicit and explicit biases. According to Dr. Dhage, implicit bias is a judgment or behavior that results from subtle cognitive processes, and the individual who holds an implicit bias is often unaware that he or she has negative perceptions of the other party. Health care professionals with implicit biases, therefore, often "unknowingly treat patients differently," she said.

> "Equality is the cornerstone of medicine," yet examples of disparities related to such factors as race, gender, sexual orientation, geography, and insurance coverage are pervasive in the spectrum of health care settings, including emergency departments. "We are taught to believe in this notion that emergency departments are 'the great equalizers.' But somehow, even in trauma centers, there are disparities."
>
> -Adil H. Haider, MD, MPH, FACS

"Do these biases affect how we treat patients? Multiple medical studies suggest that they do," said Adil H. Haider, MD, MPH, FACS, a trauma and critical care surgeon and the Kessler Director for the Center for Surgery and Public Health (CSPH), a joint initiative of Brigham and Women's Hospital, Harvard Medical School, and the Harvard T.H. Chan School of Public Health, Boston, MA; and Vice-Chair, ACS Committee on Health Care Disparities. Furthermore, "implicit biases are plausibly more significant as a basis for discrimination in contemporary American society than is outright group-directed hostility," he said.

"Equality is the cornerstone of medicine," yet examples of disparities related to such factors as race, gender, sexual orientation, geography, and insurance coverage are pervasive in the spectrum of health care settings, including emergency departments, Dr. Haider said. "We are taught to believe in this notion that emergency departments are 'the great equalizers.' But somehow, even in trauma centers, there are disparities," he said.

Although most health care professionals (more than 50 percent) believe that these inequities exist in hospitals, most don't believe the problems are detectable in their institutions. These biases exist nearly equally among surgeons, physicians, and nurses.

Health care providers are not the only ones to exhibit biases in the medical setting, Dr. Haider said. Patients also possess certain preconceived cultural notions about their health care providers that may affect their ability to access necessary care.

The ACS and the National Institutes of Health (NIH) have partnered to use a public health approach to address surgical disparities, Dr. Haider said. This methodology involves the following steps: Identify the problem, understand the mechanisms that lead to the problem, and create solutions and disseminate them.

To these ends, the ACS and the National Institute of Minority Health and Disparities (NIMHD) cohosted a symposium in May 2015 to create a national research agenda that could be used to prioritize funding for research. Prior to the meeting, Dr. Haider and other researchers conducted an extensive literature review of existing research, organized the results by theme, and asked attendees to identify what they saw as the top priorities for each theme. Over the course of the two-day symposium, more than 60 researchers, surgeon-scientists, and federal leaders used these themes to guide interactive consensus-building exercises. Symposium participants identified the following top-five research and funding priorities:

- Improve patient-provider communication by teaching providers to deliver culturally dexterous care, which Dr. Haider defined as the "adept use of mental and physical skills to understand and adapt to the unique cultural needs of the patient."
- Foster engagement and community outreach and use technology to optimize patient education, health literacy, and shared decision making in a culturally relevant way.
- Evaluate regionalization of care versus strengthening safety net hospitals within the context of differential access and surgical disparities.
- Evaluate the long-term impact of intervention and rehabilitation support within the critical period on functional outcomes and patient-defined perceptions of quality of life.
- Improve patient engagement and identify patient expectations, values, and needs.

Working together, the ACS and the NIH will design, test, and disseminate solutions to health care disparities in the U.S., Dr. Haider said.

Catherine Wagner, EdD, director, health equity curriculum, Connecticut State Medical Society, East Haddam, recapped the history of racial disparities in health care, noting that W. E. B. Du Bois was the first to cast light on the topic. In 1946, the U.S. began rebuilding hospitals, creating institutionalized "separate but equal" treatment of African-American patients. The Civil Rights Movement of the 1960s "confronted blatant racial segregation and discrimination," but did little to remove the implicit biases in health care, Dr. Wagner said.

Dr. Wagner described what she called the "ladder of oppression," which starts with stereotypes, followed by prejudice, discrimination, institutional racism, and culminates in oppression. She noted that racial minorities are less likely to receive adequate pain treatment and are less likely to seek health care services—perhaps due to a mistrust of a health care system that has historically provided unethical care to minorities.

To become more culturally dexterous health care professionals, Dr. Wagner encouraged audience members to understand the psychological basis of their biases, affirm egalitarian values, consider gut reactions, and acknowledge and reappraise, rather than suppress, their negative feelings toward people of other backgrounds.

"The most successful way to alleviate intergroup anxiety and increase provider confidence is through direct contact with members of that group," Dr. Wagner said. Consider the patient's perspective and strive to better understand how biases affect patient care.

FAQs about complying with regulatory mandates for CME

Members of the American College of Surgeons (ACS) may have questions about using their Clinical Congress experience to comply with regulatory mandates. Following are answers to commonly asked questions:

What does the College mean by credit to address regulatory mandates?

In addition to expecting physicians to earn Continuing Medical Education (CME) credit during their licensing cycle, some state licensing boards and other regulatory bodies have specific content requirements for physicians seeking CME credits. These include categories such as Ethics, Patient Safety, Pain Management, and Trauma. The ACS has developed a list of content requirements by state, available at *www.facs.org/education/cme/state-mandates*.

How do regulatory mandates affect CME offerings?

The ACS Division of Education has developed a process to formally include regulatory mandated content for CME activities. The chair of the planning committee or another physician on the committee uses his or her professional judgment to designate content to one of the eligible categories. Sessions may be advertised as offering this type of credit, and participants may claim these hours designated to specific content.

Why does the ACS CME Certificate look different than in the past?

The ACS CME Certificate now documents any approved category-specific, regulatory-mandated content credit hours that an attendee has claimed. This information is included at the bottom of the CME Certificate where it lists the Total *AMA PRA Category 1 Credits*™ claimed and the Self-Assessment Credits earned.

The disclaimer at the bottom of the CME Certificate notes that, despite a planning committee's professional judgment, it is ultimately the responsibility of the attendee to determine if the content meets the requirements for a specific regulatory mandate. The disclaimer language will only appear if an activity has been deemed to have designated content.

What is the certificate disclaimer language?

The ACS has not and does not verify the content for such mandates with any regulatory body. Individual physicians are responsible for verifying that the content satisfies such requirements.

Who can answer additional questions regarding credit to address regulatory mandates?

Contact the ACS Accreditation Team at cpda@facs.org for questions related to ACS CME applications. Contact the ACS *My*CME Team at mycme@facs.org for questions related to individual physician licensing and other regulatory requirements.

Allied Meetings

WEDNESDAY

MORNING

Surgery Editorial Board Meeting
7:00–8:30 am, Breakfast Meeting
Marriott Marquis Washington, DC, Mint, Meeting Level 4

Current Trauma Reports Editorial Board Meeting 2016
7:30–8:30 am, Breakfast Meeting
Marriott Marquis Washington, DC, Independence Ballroom Salon F, Meeting Level 4

SAGES Fundamentals Testing
8:00 am–5:00 pm, Other
Walter E. Washington Convention Center, 153, 154A, 154B, Level 1

CSA Membership Meeting
10:00–11:00 am, Meeting
Renaissance Washington, DC, Meeting Room 3, Meeting Room Level

AFTERNOON

ACS Oral and Maxillofacial Surgery Section Meeting
1:00–2:00 pm, Meeting
Marriott Marquis Washington, DC, Mint, Meeting Level 4

EVENING

CSA Council Meeting
5:00–7:00 pm, Meeting
Renaissance Washington, DC, Meeting Room 3, Meeting Room Level

FIREARM SURVEY continued from page 1

A total of 33 percent of survey respondents have personal experience with a family member or friend who has been injured or killed by a firearm; 44 percent of participants have one or more firearms in the home, and about one-third have an assault weapon in the home, according to Dr. Campbell. The top three reasons for owning a firearm are target shooting (71 percent), self-defense (66 percent), and hunting (51 percent.)

Deborah A. Kuhls, MD, FACS, presented data from the survey's "personal opinion" questions. According to Dr. Kuhls, 88 percent of the respondents said the ACS should give a "high or highest level of priority to reducing firearm-related injuries." 95 percent agreed that health care professionals should be allowed to counsel patients about firearm injury prevention, and 96.1 percent agreed that the National Institutes of Health, the CDC, and other sources should be permitted to fund research on the epidemiology and prevention of gun-related injuries.

Dr. Kuhls said the next step in the evolution of firearm injury prevention initiatives should identify gaps in the data on firearm injury and death, which will help inform targeted interventions.

Ashley B. Hink, MD, MPH, a postgraduate year-four resident and a RAS-COT Liaison, summarized the benefits and challenges of U.S. violence prevention programs. Understanding beliefs and attitudes about violence and firearm ownership should be framed like other complex public health problems, such as obesity and substance abuse, said Dr. Hink, and like those problems "multiple factors need to be addressed in order to promote change." Dr. Hink cited several violence prevention programs, such as Operation Peaceworks, Ventura, CA, and the Violence Intervention Program (VIP), Baltimore, MD, which have been shown to decrease firearm assaults and injury recidivism.

> The Firearm Owners' Privacy Act, known by some as the Physician Gag Order, "prevents providers from asking patients about gun ownership as part of routine preventive care."
>
> -Michael Coburn, MD, FACS

Support for violence prevention programs and firearm injury prevention efforts are strongly tethered to advocacy initiatives. Michael Coburn, MD, FACS, Chair of the COT Advocacy Pillar, underscored the importance of allowing federal funding for firearm injury prevention research and he specifically described the ACS participation in the "Doctors for America" letter in June, which urged Congress to lift the ban on funding for this type of research. Dr. Coburn also noted the importance of lifting the Firearm Owners' Privacy Act, also known as the "Physician Gag Order," which he said "prevents providers from asking patients about gun ownership as part of routine preventive care." The law was adopted in Florida in 2011, and there are several ongoing cases regarding this policy, which he said may go to the full 11th Circuit Court, and eventually to the U.S. Supreme Court.

In a presentation that closed the Special Session, Joseph A. Ibrahim, MD, FACS, medical director for the Level I trauma center at the Orlando Regional Medical Center (ORMC), FL, discussed lessons learned from the Pulse nightclub mass shooting on June 12. He said top leadership traits that are essential in meeting the challenges of a crisis situation include "being strong when needed, but allowing others to do their work. Trust their training and trust *your* training." Other key leadership traits include flexibility, innovation, and decisiveness—or more specifically, having one person in command.

"Grace was with us that day," said Dr. Ibrahim, noting that ORMC is located just three blocks north of the Pulse nightclub. Together with staff from Arnold Palmer Hospital, the regional pediatric hospital and part of the Level I trauma center, as well as the Winnie Palmer Hospital for Women and Babies, all of which are located on the same campus, the physicians performed 29 operative procedures and transfused 441 units of blood within 24 hours of the nightclub shooting.

Victims of a mass casualty event include the persons injured and their families, as well as the hospital caregivers. "Our disaster plan underestimated the counseling needs for such an event," said Dr. Ibrahim, noting that "multiple factors placed a significant psychological burden on our team members."

ORMC staff engaged in counseling sessions within hours of the event, and more than 2,000 team members—including trauma surgeons—participated in these sessions during the first 10 days following the Pulse nightclub shooting.

In his closing remarks, Dr. Stewart noted that sustained firearm injury prevention programs will rely on attendees working with ACS advocacy staff, engaging in dialogue between the groups on both sides of the issue, supporting violence prevention programs for trauma centers, and ultimately, focusing on the right thing to do for patients and the public.

UNIVERSAL ACCESS continued from page 3

He said Kaiser Permanente is exceeding its access goals of operating on 75 percent of elective surgery patients within six weeks of decision, as well as achieving similarly high rates of performing urgent and emergent cases in a timely manner.

The unique problems facing rural surgeons and access to care were discussed by Tyler G. Hughes, MD, FACS, general surgeon, McPherson, KS, and Chair, ACS Advisory Council for Rural Surgery (ACRS). "Despite the rural population in the U.S. being the sickest and oldest in the country, their access is declining," Dr. Hughes said. As the U.S. population becomes more centralized around large cities, once-rural surgeons are following suit, leaving the remaining population with fewer surgeons on which to rely, he said.

Dr. Hughes discussed how the ACRS was created in 2012, in part to address the looming access crisis. But he noted that "the crisis is not looming anymore." Since so much U.S. agriculture and related economic power is based on rural providers, if their access and health suffers, so too can the economy. He added that a high percentage of rural surgeons entering retirement age and a health care system that favors specialization over the rural surgeon's broad general surgery skillset contribute to a lack of rural surgeons, and spoke of some possible long-term solutions to the access problem, such as exposing surgical trainees to rural surgery early in their careers to encourage them to keep practicing in such areas.

"The best care is the best care closest to home," Dr. Hughes said, and the profession needs to work to keep that care available.

The final speaker at the session was Arthur Cooper, MD, MS, FACS, professor of surgery, Columbia University Medical Center, New York, NY, who addressed access to care in public hospitals. He explained that despite comprising only 275 hospitals, America's Essential Hospitals function as safety nets for their communities and provide roughly three times the amount of care of other community hospitals, and play a significant role in medical training. And yet, "America's Essential Hospitals provide close to 20 percent of all uncompensated care nationwide," Dr. Cooper said.

> "The best care is the best care closest to home."
>
> -Tyler G. Hughes, MD, FACS

"Sadly, with the loss of the Disproportionate Share funding with the Affordable Care Act, the safety net hospitals are going to take a substantial hit," Dr. Cooper explained. Since these hospitals provide a high volume of care, including essential and emergency surgical procedures, community access to surgical care will be significantly diminished if they close.

Real-world evidence necessary for optimal patient care

Randomized clinical trials are the gold standard for clinical evidence, but only 3 percent of U.S. cancer patients enroll in clinical trials. Clinicians need the vital insights that can be gleaned from the other 97 percent of patients in order to improve cancer care for all, according to Richard L. Schilsky, MD, FACP, FASCO, senior vice-president and chief medical officer of the American Society of Clinical Oncology (ASCO), Alexandria, VA.

"We have traditionally learned most of what we know about what can work in treating cancer from controlled clinical trials," Dr. Schilsky said. "But given the enormous diversity of the cancer population and the expense and time that it takes to launch and complete clinical trials, we cannot rely on clinical trials as the only learning vehicle. We need to be able to learn from real-world data sources."

Dr. Schilsky will explore the challenges and opportunities of real-world evidence during Wednesday's Commission on Cancer Oncology Lecture, Finding the Evidence in Real-World Evidence: Moving from Data to Information to Knowledge. Clinical trials data and real world data are not identical, but both can and must inform treatment decisions, he said.

Richard L. Schilsky, MD, FACP, FASCO

> "What we get from clinical trials data is the best possible outcome for a new intervention in a very carefully defined population. What we get from real world evidence is how well that intervention actually works in clinical practice. It's the dichotomy between what can work in a clinical trial and what does work in clinical practice."

"What we get from clinical trials data is the best possible outcome for a new intervention in a very carefully defined population," Dr. Schilsky said. "What we get from real world evidence is how well that intervention actually works in clinical practice. It's the dichotomy between what can work in a clinical trial and what does work in clinical practice."

Designing, conducting, running, and analyzing a clinical trial can take five to 10 years and hundreds of millions of dollars, Dr. Schilsky noted. That gargantuan effort may, at best, answer a single question in a single, very narrowly defined patient population.

Meanwhile, massive amounts of data from clinical trials, registries, electronic health records, inpatient and outpatient claims, and pharmacy claims accumulate every day. But the ability to collect and store big data has far outstripped the ability to organize and analyze unconnected bits of information to produce useful knowledge, Dr. Schilsky said.

ASCO launched medicine's most ambitious cancer analytics program earlier this year. Cancer Learning Intelligence Network for Quality (CancerLinQ) is the only major cancer data-sharing initiative being developed and led by physicians, Dr. Schilsky said. The platform combines, anonymizes, and analyzes cancer treatment data from any electronic health record source to provide the latest information on treatments, trends, and results for almost any intervention, tumor type, or genomic profile. The result is actionable information that can help physicians personalize treatment to every patient at the point of care.

"We have an opportunity today to access and organize more cancer care data than has ever existed before, and we have the opportunity to distill from that data information that can actually help us to improve the quality of care at the point of care," Dr. Schilsky said.

The Commission on Cancer Oncology Lecture is sponsored by the Commission on Cancer. It was established in 1988 to explore major developments in oncology and to focus on the surgeon's role in caring for cancer patients.

COMMISSION ON CANCER ONCOLOGY LECTURE

Finding the Evidence in Real-World Evidence: Moving from Data to Information to Knowledge

Richard L. Schilsky, MD, FACP, FASCO

12:45–1:45 pm, Wednesday

Walter E. Washington Convention Center, Ballroom B

There's still time to see the new edition of *SESAP*®

The newly released edition of the *Surgical Education and Self-Assessment Program* (*SESAP*®) is available for viewing in the American College of Surgeons (ACS) Resource Center in the Walter E. Washington Convention Center, Hall B. *SESAP 16*, developed by the ACS Division of Education, upholds the program's 45-year tradition of providing the highest-quality, peer-reviewed, evidence-based content to promote excellence and expertise in surgery.

SESAP 16 features 850 newly constructed multiple-choice questions in 14 major areas of general surgery consistent with the American Board of Surgery outline for topics addressed in recertification exams. Participants can earn up to 90 *AMA PRA Category 1 Credits*™, all of which can be used for self-assessment purposes and can be claimed immediately after completing each category or all at once. The iterative model used for Continuing Medical Education (CME) credits reinforces learning and supports mastery of the content. For the first time, users will have the added convenience of being able to exit the program without completing a section and, upon re-entering, will be returned to the same point in the program.

SESAP 16 is available in a variety of formats. To earn CME credit, participants must use the *SESAP 16* CME website or its mobile apps. The *SESAP 16* print version is available as a supplement to the electronic versions. A NonCME print version is available, which includes the two-volume syllabus, self-assessment book, and self-scoring booklet. A NonCME Web version also is available, with or without the print edition. All options include access to mobile applications (iPads, Android tablets, iPhones, and Android phones).

New ACS/ASBrS scholarship applications due November 15

The new American College of Surgeons (ACS)/American Society of Breast Surgeons (ASBrS) International Scholarship will be awarded to surgeons working in breast cancer surgery in countries other than the U.S. and Canada. Applications are due **Tuesday, November 15**. Applicants from developing nations will receive preference for the scholarships, which are intended to improve the quality of breast cancer services. The $5,000 scholarship will support the scholar's attendance at the ASBrS annual meeting as well as a visit to the National Accreditation Program for Breast Centers headquarters in Chicago, IL, to learn about the standards for a breast cancer program/database and the importance of multidisciplinary breast cancer care. The awardee will receive free registration to the ASBrS annual meeting and to one available postgraduate course at the meeting. See full description and link to application form at *www.facs.org/member-services/scholarships/international/acsasbrs-intl*.

Let us know about your Clinical Congress educational experience

The American College of Surgeons (ACS) Division of Education anticipates that Clinical Congress 2016 attendees will take advantage of the myriad sessions available to support surgeons in achieving their personal best and improving their professional practice. This is your meeting, and the Division of Education and Clinical Congress Program Committee want to hear from you. A convenient way to do so is by completing the Global Evaluation, which is required in order to claim Continuing Medical Education (CME) credit. The Global Evaluation can be found at the end of the CME credit claiming process.

Claiming CME credit, earning Self-Assessment credit, and completing the Global Evaluation can all be done at the *My*CME booth on the Concourse Level of the Walter E. Washington Convention Center (adjacent to the Marriott Marquis walkway), at the *My*CME booth in the ACS Resource Center, Hall B, in front of 150, in front of the third floor ballroom, and next to the L Street Bridge. Physicians may claim a maximum of 8.5 CME credits and earn 7.5 Self-Assessment credits on Wednesday, and an additional 3 CME credits and 3 Self-Assessment credits on Thursday.

Many of the sessions scheduled to take place Wednesday and Thursday will provide Self-Assessment credits and may be used to fulfill state regulatory-mandated content requirements. Consider attending any of the following sessions on the Clinical Congress 2016 schedule:

WEDNESDAY

Cultural Competency (Connecticut and New Jersey)
Panel Session: The Enduring Impact of Three African-American Surgical Pioneers
(up to 1.5 CME credit hours in Cultural Competency)
12:45–2:15 pm
Walter E. Washington Convention Center, 206

Ethics (Florida Osteopaths, Nevada, Rhode Island, Texas)
Didactic/Experiential Course: Innovation and Invention in Surgery
(up to 6.0 CME credit hours in Ethics) (Note: this is a ticketed session)
8:30 am–4:00 pm
Walter E. Washington Convention Center, 103A

Named Lecture: John J. Conley Ethics and Philosophy Lecture
(up to 1.0 CME credit hour in Ethics)
9:45–10:45 am
Walter E. Washington Convention Center, 201

Pain Management (California, Connecticut, Iowa [primary care MD, DO only], Kentucky, Massachusetts, Maryland, New Mexico, Nevada, Oregon, Rhode Island, Texas, Vermont)
Didactic/Experiential Course: Maintenance of Certification (MOC): Essentials for Surgical Specialties
(up to 4.0 CME credit hours in Pain Management) (Note: This is a ticketed session)
8:00 am–12:15 pm
Walter E. Washington Convention Center, 151A

Patient Safety (Pennsylvania)
Panel Session: Cholecystectomy 2016: Achieving a Culture of Safety
(up to 1.5 CME credit hours in Patient Safety)
8:00–9:30 am
Walter E. Washington Convention Center, Hall D

Risk Management (Connecticut, Massachusetts, Rhode Island)
Panel Session: Appendicitis: Why Haven't We Figured Out Who to Operate On, What to Treat Non-operatively, or Who to Drain Percutaneously?
(up to 1.5 CME credit hours in Risk Management)
2:30–4:00 pm
Walter E. Washington Convention Center, Ballroom C

Trauma
Panel Session: Compartment Syndrome: What Every Surgeon Should Know
(up to 1.5 CME credit hours in Trauma)
8:00–9:30 am
Walter E. Washington Convention Center, Ballroom C

Panel Session: Coagulopathy: Old Problems/New Solutions
(up to 1.5 CME credit hours in Trauma)
12:45–2:15 pm
Walter E. Washington Convention Center, Ballroom C

THURSDAY

Patient Safety (Pennsylvania)
Panel Session: Ten Hot Topics in General Surgery
(up to 1.5 CME credit hours in Patient Safety)
8:00–9:30 am
Walter E. Washington Convention Center, Ballroom A

Panel Session: Ten Hot Topics in Critical Care
(up to 1.5 CME credit hours in Patient Safety)
9:45–11:15 am
Walter E. Washington Convention Center, 150

Over the next two days, the *My*CME booth on the Concourse level next to the bridge to the Marriott Marquis will be very busy because the Exhibit Hall location will be closing at 4:30 pm Wednesday. As a reminder, you may also claim credit on your smartphone, tablet, or computer. Simply go to *www.cme.facs.org*. Log in using your Registration ID (located on the lower left side of your badge) and password (your last name). Members can also log in using their ACS Member ID and password. If you have questions, please contact the *My*CME office after Friday, October 21, at 1-866-918-4799 or mycme@facs.org.

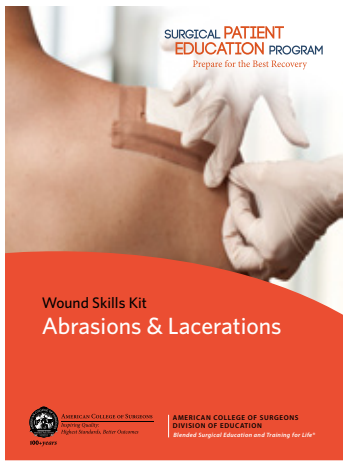
The deadline to claim CME credit, earn Self-Assessment credit, and claim hours that may satisfy additional regulatory mandates is December 1, 2016.

Patient education materials on in-home wound care aimed at reducing surgical site wound infections

Extensive focus has been placed on reducing surgical site infections (SSIs) and complication rates in the intensive care unit and among hospitalized patients. However, little emphasis has been placed on helping patients and their families manage wound care post-discharge, or making resources available to the professional who wants to educate patients on in-home wound care. And the fact is, patients overwhelmingly choose their physicians as their primary source of information about wound care, yet more than 50 percent leave with no wound care instruction.[1]

Approximately 60 percent of wounds managed in the home are surgical. In all of home care, 50 percent of cases involve complex wound management.[2,3] Given that wound care constitutes such a high volume of service and consumes such a large percentage of finite human and financial resources, it is imperative that wound care be safe, effective, and efficient.

The American Hospital Association's Health Research and Education Trust recently noted that inadequate patient education in postoperative wound care is a significant contributor to avoidable readmissions. Other studies show that 63 percent of patients who did not receive wound care information returned to their health care facilities after discharge due to wound-related issues they were uncertain how to handle.[4-6]



The American College of Surgeons (ACS) established the first multidisciplinary workgroup to develop a program that will cover in-home care for abrasions, lacerations, and surgical wounds. These patient education materials follow a skill acquisition model that includes information about the skin and wound healing, wound type, and home management instruction with image-driven, step-by-step guides. This standardized, skill-based home care education and evaluation program uses health literacy-appropriate language and images to educate patients.

Although the number of groups that certify professionals in wound care management continues to grow, no discharge/home care plans or evaluation systems are available to determine the impact on patient care outcomes. This dearth is significant because patients discharged with a wound want information on how to avert pain and possible complications, including the signs of infection.[1] Yet 38 percent of these individuals did not know how to change a dressing, more than half (58 percent) did not know what solution to use to clean the wound, and more than half were discharged with no specific wound care instruction.[1-2] The ACS is hoping to change that with this new program.

For more information, visit the Patient Education booth in the ACS Resource Center at the Walter E. Washington Convention Center, Hall B, or contact *abruggeman@facs.org*.

1. Pieper B, Siggreen M, Nordstrom CK, et al. Discharge knowledge and concerns of patients going home with a wound. J Wound, Ostomy Continence Nurs. 2007;34(3):245-253.
2. Chen, Lee-ling. A retrospective chart review of hospital based wound discharge planning and 30-day readmission rates. Master's thesis. Available at *https://digital.lib.washington.edu/researchworks/bitstream/handle/1773/24078/Chen_washington_0250O_12368.pdf?sequence=1*. Accessed September 16, 2016
3. Agency for Health Care Research and Quality. Guide to Patient and Family Engagement in Hosptial Quality and Safety, June 2013. U.S. Department of Health and Human Services. Available at *www.ahrq.gov/professionals/systems/hospital/engagingfamilies/guide.html*. Accessed September 11, 2016.
4. McNaughton V, Orsted H. Surgical site infections in community care clients. *Wound Care Canada*. 2005;3(1):10-13.
5. American College of Wound Healing and Tissue Repair and the Angiogenesis Foundation. Patient Centered Outcomes in Wound Care White Paper, December 2013. Available at *www.angio.org/wp-content/uploads/2013/10/Wound_Care_White_Paper.pdf*. Accessed September 16, 2016.
6. Henderson A, Zernike W. 2001. A study of the impact of discharge information for surgical patients. *J Adv Nurs*. 2001;35(3):435-441.

In clinical trials, ENTEREG added to an accelerated care pathway (ACP), also commonly called an enhanced recovery pathway (ERP),[1,2] was more effective than an ACP alone in helping to

» ACCELERATE GI RECOVERY

The ACP used in clinical trials included:

- Early diet advancement
- Early nasogastric tube (NGT) removal
- Early ambulation

Indication and Usage

ENTEREG is indicated to accelerate the time to upper and lower gastrointestinal recovery following surgeries that include partial bowel resection with primary anastomosis.

Important Safety Information

WARNING: POTENTIAL RISK OF MYOCARDIAL INFARCTION WITH LONG-TERM USE: FOR SHORT-TERM HOSPITAL USE ONLY

- **Increased incidence of myocardial infarction was seen in a clinical trial of patients taking alvimopan for long-term use. No increased risk was observed in short-term trials.**
- **Because of the potential risk of myocardial infarction, ENTEREG is available only through a restricted program for short-term use (15 doses) called the ENTEREG Access Support and Education (E.A.S.E.) Program.**

Contraindications

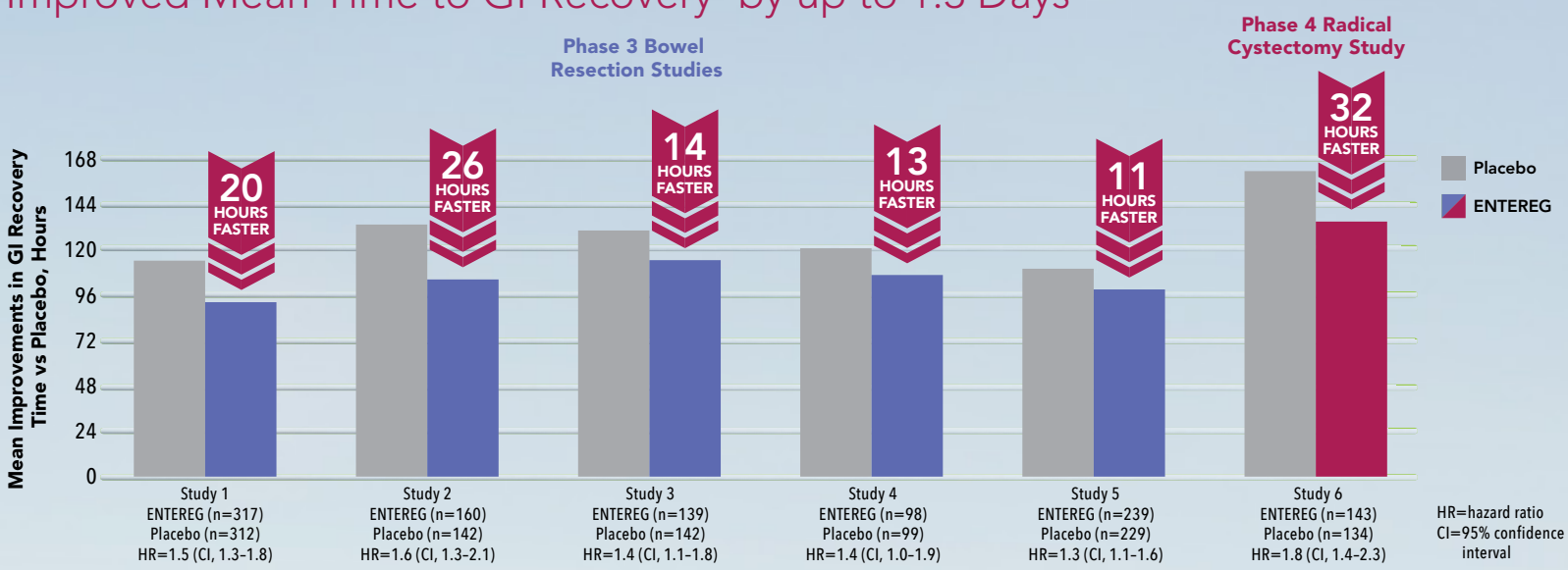
- ENTEREG Capsules are contraindicated in patients who have taken therapeutic doses of opioids for more than 7 consecutive days immediately prior to taking ENTEREG.

Warnings and Precautions

- There were more reports of myocardial infarctions in patients treated with alvimopan 0.5 mg twice daily compared with placebo-treated patients in a 12-month study of patients treated with opioids for chronic pain. In this study, the majority of myocardial infarctions occurred between 1 and 4 months after initiation of treatment. This imbalance has not been observed in other studies of alvimopan, including studies of patients undergoing bowel resection surgery who received alvimopan 12 mg twice daily for up to 7 days. A causal relationship with alvimopan has not been established.

For Patients Undergoing Partial Bowel Resections With Primary Anastomosis

Adding ENTEREG to an Accelerated Postoperative Care Pathway Improved Mean Time to GI Recovery[a] by up to 1.3 Days[3]



[a]GI recovery was defined as the time to toleration of solid food and first bowel movement.

Median time to GI recovery was improved with use of ENTEREG by 17 hours (Study 1, Study 2), 15 hours (Study 3), 12 hours (Study 4), and 3 hours (Study 5) in the phase 3 bowel resection studies and 29 hours in the phase 4 radical cystectomy study (Study 6).[3] Patient numbers are for modified ITT; dose of ENTEREG used was 12 mg.

Study Design

Data are from 5 multicenter, randomized, double-blind, parallel-group, placebo-controlled studies in patients undergoing bowel resection and 1 randomized, double-blind, placebo-controlled study in patients undergoing radical cystectomy (5 US studies and 1 non-US bowel resection study; ENTEREG: n=1096; placebo: n=1058; 54% male; 89% Caucasian).

Patients 18 years of age or older (average age: 62 years) who underwent bowel resection surgeries that included primary anastomosis (partial large or small bowel resection surgery or radical cystectomy for bladder cancer) were administered ENTEREG 12 mg or placebo 30 minutes to 5 hours prior to surgery and twice daily after surgery until discharge, for a maximum of 7 days.

There were no limitations on the types of general anesthesia used.

The primary endpoint for all studies was time to achieve resolution of postoperative ileus, a clinically defined composite measure of both upper and lower GI recovery. GI2 (toleration of solid food and first bowel movement) represents the most objective and clinically relevant measure of treatment response.

The efficacy of ENTEREG following total abdominal hysterectomy has not been established.

Study Exclusions

Patients who received more than 3 doses of an opioid (regardless of route) during the 7 days prior to surgery and patients with complete bowel obstruction or who were scheduled for a total colectomy, colostomy, or ileostomy were excluded. Intrathecal or epidural opioids or anesthetics were prohibited.

Important Safety Information

Warnings and Precautions *(continued)*

- E.A.S.E. Program for ENTEREG: ENTEREG is available only to hospitals that enroll in the E.A.S.E. ENTEREG REMS Program. To enroll in the E.A.S.E. Program, the hospital must acknowledge that:
  - Hospital staff who prescribe, dispense, or administer ENTEREG have been provided the educational materials on the need to limit use of ENTEREG to short-term, inpatient use
  - Patients will not receive more than 15 doses of ENTEREG
  - ENTEREG will not be dispensed to patients after they have been discharged from the hospital
- ENTEREG should be administered with caution to patients receiving more than 3 doses of an opioid within the week prior to surgery. These patients may be more sensitive to ENTEREG and may experience GI side effects (eg, abdominal pain, nausea and vomiting, diarrhea).
- ENTEREG is not recommended for use in patients with severe hepatic impairment, end-stage renal disease, complete gastrointestinal obstruction, or pancreatic or gastric anastomosis, or in patients who have had surgery for correction of complete bowel obstruction.

Adverse Reactions

- The most common adverse reaction (incidence ≥1.5%) occurring with a higher frequency than placebo among ENTEREG-treated patients undergoing surgeries that included a bowel resection was dyspepsia (ENTEREG, 1.5%; placebo, 0.8%).

Please read the adjacent Brief Summary of the Prescribing Information, including the Boxed Warning about potential risk of myocardial infarction with long-term use.

For Patients Undergoing Surgeries That Include Partial Bowel Resection With Primary Anastomosis

Make ENTEREG Part of Your Pre- and Postsurgical Protocols

References: 1. Berger NG, Ridolfi TJ, Ludwig KA. Delayed gastrointestinal recovery after abdominal operation—role of alvimopan. *Clin Exp Gastroenterol.* 2015;8:231- 235. **2.** Melnyk M, Casey RG, Black P, Koupparis AJ. Enhanced recovery after surgery (ERAS) protocols: time to change practice? *Can Urol Assoc J.* 2011;5(5):342-348. **3.** Data available on request from Merck & Co., Inc., Professional Services-DAP, WP1-27, PO Box 4, West Point, PA 19486-0004. Please specify information package ANES-1149074-0001.

ENTEREG® (alvimopan) capsules, 12 mg

MERCK

ENTEREG® (alvimopan) capsules 12 mg, for oral use

BRIEF SUMMARY OF PRESCRIBING INFORMATION

WARNING: POTENTIAL RISK OF MYOCARDIAL INFARCTION WITH LONG-TERM USE: FOR SHORT-TERM HOSPITAL USE ONLY

There was a greater incidence of myocardial infarction in alvimopan-treated patients compared to placebo-treated patients in a 12-month clinical trial, although a causal relationship has not been established. In short-term trials with ENTEREG, no increased risk of myocardial infarction was observed.

Because of the potential risk of myocardial infarction with long-term use, ENTEREG is available only through a restricted program for short-term use (15 doses) under a Risk Evaluation and Mitigation Strategy (REMS) called the ENTEREG Access Support and Education (E.A.S.E.®) Program.

DOSAGE AND ADMINISTRATION

For hospital use only. The recommended adult dosage of ENTEREG is 12 mg administered 30 minutes to 5 hours prior to surgery followed by 12 mg twice daily beginning the day after surgery until discharge for a maximum of 7 days. Patients should not receive more than 15 doses of ENTEREG.

CONTRAINDICATIONS

ENTEREG is contraindicated in patients who have taken therapeutic doses of opioids for more than 7 consecutive days immediately prior to taking ENTEREG.

WARNINGS AND PRECAUTIONS

Potential Risk of Myocardial Infarction with Long-term Use

There were more reports of myocardial infarctions in patients treated with alvimopan 0.5 mg twice daily compared with placebo-treated patients in a 12-month study of patients treated with opioids for chronic non-cancer pain (alvimopan 0.5 mg, n = 538; placebo, n = 267). In this study, the majority of myocardial infarctions occurred between 1 and 4 months after initiation of treatment. This imbalance has not been observed in other studies of ENTEREG in patients treated with opioids for chronic pain, nor in patients treated within the surgical setting, including patients undergoing surgeries that included bowel resection who received ENTEREG 12 mg twice daily for up to 7 days (the indicated dose and patient population; ENTEREG 12 mg, n = 1,142; placebo, n = 1,120). A causal relationship with alvimopan with long-term use has not been established.

ENTEREG is available only through a program under a REMS that restricts use to enrolled hospitals.

E.A.S.E. ENTEREG REMS Program

ENTEREG is available only through a program called the ENTEREG Access Support and Education (E.A.S.E.) ENTEREG REMS Program that restricts use to enrolled hospitals because of the potential risk of myocardial infarction with long-term use of ENTEREG.

Notable requirements of the E.A.S.E. Program include the following:

ENTEREG is available only for short-term (15 doses) use in hospitalized patients. Only hospitals that have enrolled in and met all of the requirements for the E.A.S.E. program may use ENTEREG.

To enroll in the E.A.S.E. Program, an authorized hospital representative must acknowledge that:

- hospital staff who prescribe, dispense, or administer ENTEREG have been provided the educational materials on the need to limit use of ENTEREG to short-term, inpatient use;
- patients will not receive more than 15 doses of ENTEREG; and
- ENTEREG will not be dispensed to patients after they have been discharged from the hospital.

Further information is available at www.ENTEREGREMS.com or 1-800-278-0340.

Gastrointestinal-Related Adverse Reactions in Opioid-Tolerant Patients

Patients recently exposed to opioids are expected to be more sensitive to the effects of μ-opioid receptor antagonists, such as ENTEREG. Since ENTEREG acts peripherally, clinical signs and symptoms of increased sensitivity would be related to the gastrointestinal tract (e.g., abdominal pain, nausea and vomiting, diarrhea). Patients receiving more than 3 doses of an opioid within the week prior to surgery were not studied in the postoperative ileus clinical trials. Therefore, if ENTEREG is administered to these patients, they should be monitored for gastrointestinal adverse reactions. ENTEREG is contraindicated in patients who have taken therapeutic doses of opioids for more than 7 consecutive days immediately prior to taking ENTEREG.

Risk of Serious Adverse Reactions in Patients with Severe Hepatic Impairment

Patients with severe hepatic impairment may be at higher risk of serious adverse reactions (including dose-related serious adverse reactions) because up to 10-fold higher plasma levels of drug have been observed in such patients compared with patients with normal hepatic function. Therefore, the use of ENTEREG is not recommended in this population.

End-Stage Renal Disease

No studies have been conducted in patients with end-stage renal disease. ENTEREG is not recommended for use in these patients.

Risk of Serious Adverse Reactions in Patients with Complete Gastrointestinal Obstruction

No studies have been conducted in patients with complete gastrointestinal obstruction or in patients who have surgery for correction of complete bowel obstruction. ENTEREG is not recommended for use in these patients.

Risk of Serious Adverse Reactions in Pancreatic and Gastric Anastomoses

ENTEREG has not been studied in patients having pancreatic or gastric anastomosis. Therefore, ENTEREG is not recommended for use in these patients.

ADVERSE REACTIONS

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be compared directly with rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice. The adverse event information from clinical trials does, however, provide a basis for identifying the adverse events that appear to be related to drug use and for approximating rates. The data described below reflect exposure to ENTEREG 12 mg in 1,793 patients in 10 placebo-controlled studies. The population was 19 to 97 years old, 64% were female, and 84% were Caucasian; 64% were undergoing a surgery that included bowel resection. The first dose of ENTEREG was administered 30 minutes to 5 hours before the scheduled start of surgery and then twice daily until hospital discharge (or for a maximum of 7 days of postoperative treatment).

Among ENTEREG-treated patients undergoing surgeries that included a bowel resection, the most common adverse reaction (incidence ≥1.5%) occurring with a higher frequency than placebo was dyspepsia (ENTEREG, 1.5%; placebo, 0.8%). Adverse reactions are events that occurred after the first dose of study medication treatment and within 7 days of the last dose of study medication or events present at baseline that increased in severity after the start of study medication treatment.

DRUG INTERACTIONS

Potential for Drugs to Affect Alvimopan Pharmacokinetics

An *in vitro* study indicates that alvimopan is not a substrate of CYP enzymes. Therefore, concomitant administration of ENTEREG with inducers or inhibitors of CYP enzymes is unlikely to alter the metabolism of alvimopan.

Potential for Alvimopan to Affect the Pharmacokinetics of Other Drugs

Based on *in vitro* data, ENTEREG is unlikely to alter the pharmacokinetics of coadministered drugs through inhibition of CYP isoforms such as 1A2, 2C9, 2C19, 3A4, 2D6, and 2E1 or induction of CYP isoforms such as 1A2, 2B6, 2C9, 2C19, and 3A4. *In vitro*, ENTEREG did not inhibit p-glycoprotein.

Effects of Alvimopan on Intravenous Morphine

Coadministration of alvimopan does not appear to alter the pharmacokinetics of morphine and its metabolite, morphine-6-glucuronide, to a clinically significant degree when morphine is administered intravenously. Dosage adjustment for intravenously administered morphine is not necessary when it is coadministered with alvimopan.

Effects of Concomitant Acid Blockers or Antibiotics

A population pharmacokinetic analysis suggests that the pharmacokinetics of alvimopan were not affected by concomitant administration of acid blockers or antibiotics. No dosage adjustments are necessary in patients taking acid blockers or antibiotics.

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Category B

Risk Summary: There are no adequate and/or well-controlled studies with ENTEREG in pregnant women. No fetal harm was observed in animal reproduction studies with oral administration of alvimopan to rats at doses 68 to 136 times the recommended human oral dose, or with intravenous administration to rats and rabbits at doses 3.4 to 6.8 times, and 5 to 10 times, respectively, the recommended human oral dose. Because animal reproduction studies are not always predictive of human response, ENTEREG should be used during pregnancy only if clearly needed.

Animal Data: Reproduction studies were performed in pregnant rats at oral doses up to 200 mg/kg/day (about 68 to 136 times the recommended human oral dose based on body surface area) and at intravenous doses up to 10 mg/kg/day (about 3.4 to 6.8 times the recommended human oral dose based on body surface area) and in pregnant rabbits at intravenous doses up to 15 mg/kg/day (about 5 to 10 times the recommended human oral dose based on body surface area), and revealed no evidence of impaired fertility or harm to the fetus due to alvimopan.

Nursing Mothers

It is not known whether ENTEREG is present in human milk. Alvimopan and its 'metabolite' are detected in the milk of lactating rats. Exercise caution when administering ENTEREG to a nursing woman.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use

Of the total number of patients in 6 clinical efficacy studies treated with ENTEREG 12 mg or placebo, 46% were 65 years of age and over, while 18% were 75 years of age and over. No overall differences in safety or effectiveness were observed between these patients and younger patients, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out. No dosage adjustment based on increased age is required.

Hepatic Impairment

ENTEREG is not recommended for use in patients with severe hepatic impairment.

Dosage adjustment is not required for patients with mild-to-moderate hepatic impairment. Patients with mild-to-moderate hepatic impairment should be closely monitored for possible adverse effects (e.g., diarrhea, gastrointestinal pain, cramping) that could indicate high drug or 'metabolite' levels, and ENTEREG should be discontinued if adverse events occur.

Renal Impairment

ENTEREG is not recommended for use in patients with end-stage renal disease. Dosage adjustment is not required for patients with mild-to-severe renal impairment, but they should be monitored for adverse effects. Patients with severe renal impairment should be closely monitored for possible adverse effects (e.g., diarrhea, gastrointestinal pain, cramping) that could indicate high drug or 'metabolite' levels, and ENTEREG should be discontinued if adverse events occur.

Race

No dosage adjustment is necessary in Black, Hispanic, and Japanese patients. However, the exposure to ENTEREG in Japanese healthy male volunteers was approximately 2-fold greater than in Caucasian subjects. Japanese patients should be closely monitored for possible adverse effects (e.g., diarrhea, gastrointestinal pain, cramping) that could indicate high drug or 'metabolite' levels, and ENTEREG should be discontinued if adverse events occur.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis: Two-year carcinogenicity studies were conducted with alvimopan in CD-1 mice at oral doses up to 4000 mg/kg/day and in Sprague-Dawley rats at oral doses up to 500 mg/kg/day. Oral administration of alvimopan for 104 weeks produced significant increases in the incidences of fibroma, fibrosarcoma, and sarcoma in the skin/subcutis, and of osteoma/osteosarcoma in bones of female mice at 4000 mg/kg/day (about 674 times the recommended human dose based on body surface area). In rats, oral administration of alvimopan for 104 weeks did not produce any tumor up to 500 mg/kg/day (about 166 times the recommended human dose based on body surface area).

Mutagenesis: Alvimopan was not genotoxic in the Ames test, the mouse lymphoma cell (L5178Y/TK$^{+/-}$) forward mutation test, the Chinese Hamster Ovary (CHO) cell chromosome aberration test, or the mouse micronucleus test. The pharmacologically active 'metabolite' ADL 08-0011 was negative in the Ames test, chromosome aberration test in CHO cells, and mouse micronucleus test.

Impairment of Fertility: Alvimopan at intravenous doses up to 10 mg/kg/day (about 3.4 to 6.8 times the recommended human oral dose based on body surface area) was found to have no adverse effect on fertility and reproductive performance of male or female rats.

PATIENT COUNSELING INFORMATION

Recent Use of Opioids

Patients should be informed that they must disclose long-term or intermittent opioid pain therapy, including any use of opioids in the week prior to receiving ENTEREG. They should understand that recent use of opioids may make them more susceptible to adverse reactions to ENTEREG, primarily those limited to the gastrointestinal tract (e.g., abdominal pain, nausea and vomiting, diarrhea).

Hospital Use Only

ENTEREG is available only through a program called the ENTEREG Access Support and Education (E.A.S.E.) Program under a REMS that restricts use to enrolled hospitals because of the potential risk of myocardial infarction with long-term use of ENTEREG. Patients should be informed that ENTEREG is for hospital use only for no more than 7 days after their bowel resection surgery.

Most Common Side Effect

Patients should be informed that the most common side effect with ENTEREG in patients undergoing surgeries that include bowel resection is dyspepsia.

For more detailed information, please read the Prescribing Information.

USPI-MK3753-C-1508R000
Revised: 08/2015

CLINICAL CONGRESS NEWS & NOTES

Registration Location and Hours
An official registration badge is required for entrance to all sessions and to the Exhibit Hall. Registration location and hours are as follows:

Walter E. Washington Convention Center, Hall A, Lower Level
7:00 am–4:00 pm, Wednesday
7:00–10:00 am, Thursday

Special Session
Special Sessions at Clinical Congress 2016 provide an in-depth look at timely and important topics. There is no charge for these sessions, which will be presented during the lunch hour. Attendees will have an opportunity to purchase lunch prior to entering the session. Wednesday's session is:

Global Engagement
11:15 am–12:45 pm, Wednesday
Walter E. Washington Convention Center, Ballroom C

Surgical History Group: History of Surgery Poster Session
The History of Surgery Poster Session highlights the rich history of surgery and is presented by Fellows, residents, and medical students. These posters will be on display until 4:30 pm Wednesday in the Walter E. Washington Convention Center, Hall B.

Scientific Forum Poster Presentations
The Scientific Poster Presentations is a forum of more than 300 posters showcasing timely, innovative information and findings on original scientific research, surgical practices, and approaches. The Scientific Forum Poster Presentations will be available until 4:30 pm Wednesday in the Walter E. Washington Convention Center, Hall B.

Update your FACS Profile
Visit the Photo and Public Profile booth in the American College of Surgeons (ACS) Resource Center to get a complimentary photo, and be sure to take advantage of this opportunity to work with staff to update your member profile on the ACS website. The ACS Find a Surgeon site helps the public connect with qualified surgeons by providing access to College member profiles. Your personalized profile may include information about your practice site, medical school, residency, fellowships, and areas of special interest and expertise.

First Aid/Lactation Room
Two first aid offices/lactation rooms are located in the Walter E. Washington Convention Center, one in Hall A and one in Hall D. Both rooms are accessible from inside the halls.

Friends of Bill W.
Friends of Bill W. will meet 7:00–8:30 pm Wednesday at the Marriott Marquis, Pentagon Room, Level Four.

Bistro ACS
Grab lunch and network with exhibitors and colleagues at Bistro ACS in the Exhibit Hall at the Walter E. Washington Convention Center, Hall B, Lower Level. Open through Wednesday, Bistro ACS provides an excellent opportunity for uninterrupted face-to-face time between attendees and exhibiting companies.

Bistro ACS offers assorted menu choices, including several fresh and healthy options, international cuisine, and regional favorites. It's reasonably priced for an all-inclusive lunch buffet; $25 includes lunch, beverages, dessert, and tax. Bistro ACS also provides attendees with express seating and is conveniently located. Tickets may be purchased daily at the Bistro ACS booth at the Walter E. Washington Convention Center, Hall A, or online at *http://bistroticket.com/acs.*

Lost and Found
Lost and Found areas are located in the ACS Convention Office at the Marriott Marquis and in the Convention and Exhibit Office at the Walter E. Washington Convention Center, Hall A.

ACS Logo Merchandise
ACS exclusive logo merchandise is available for purchase at the Logo Merchandise Booth in the Walter E. Washington Convention Center, Hall B. Hours of operation are 9:00 am–4:30 pm.

Prayer Room
A prayer room is available throughout the meeting and is located at the Walter E. Washington Convention Center, 210.

CLINICAL CONGRESS 2016 TECHNICAL EXHIBITION

WALTER E. WASHINGTON CONVENTION CENTER, HALL B

HOURS

9:00 am–4:30 pm, Wednesday

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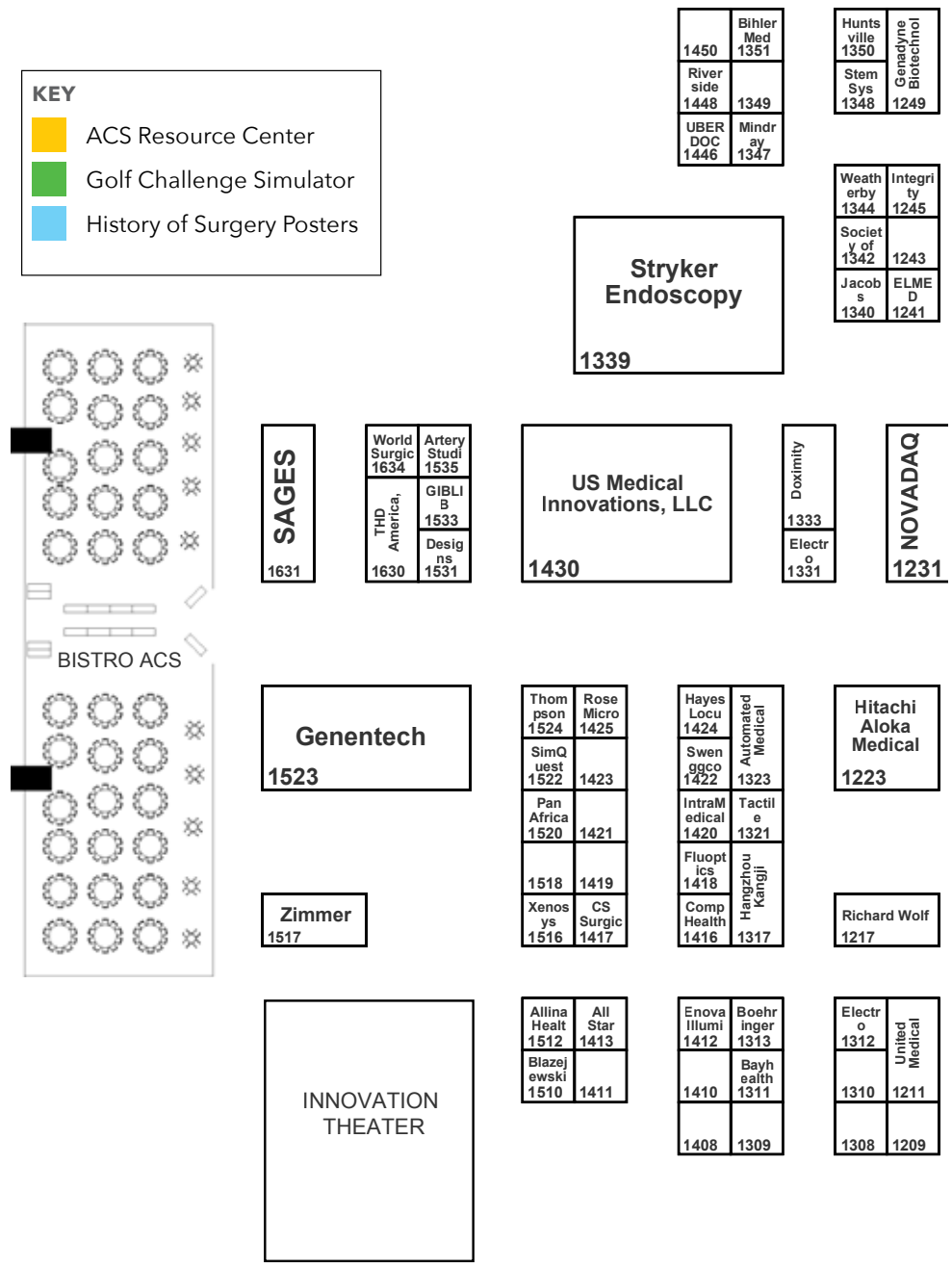

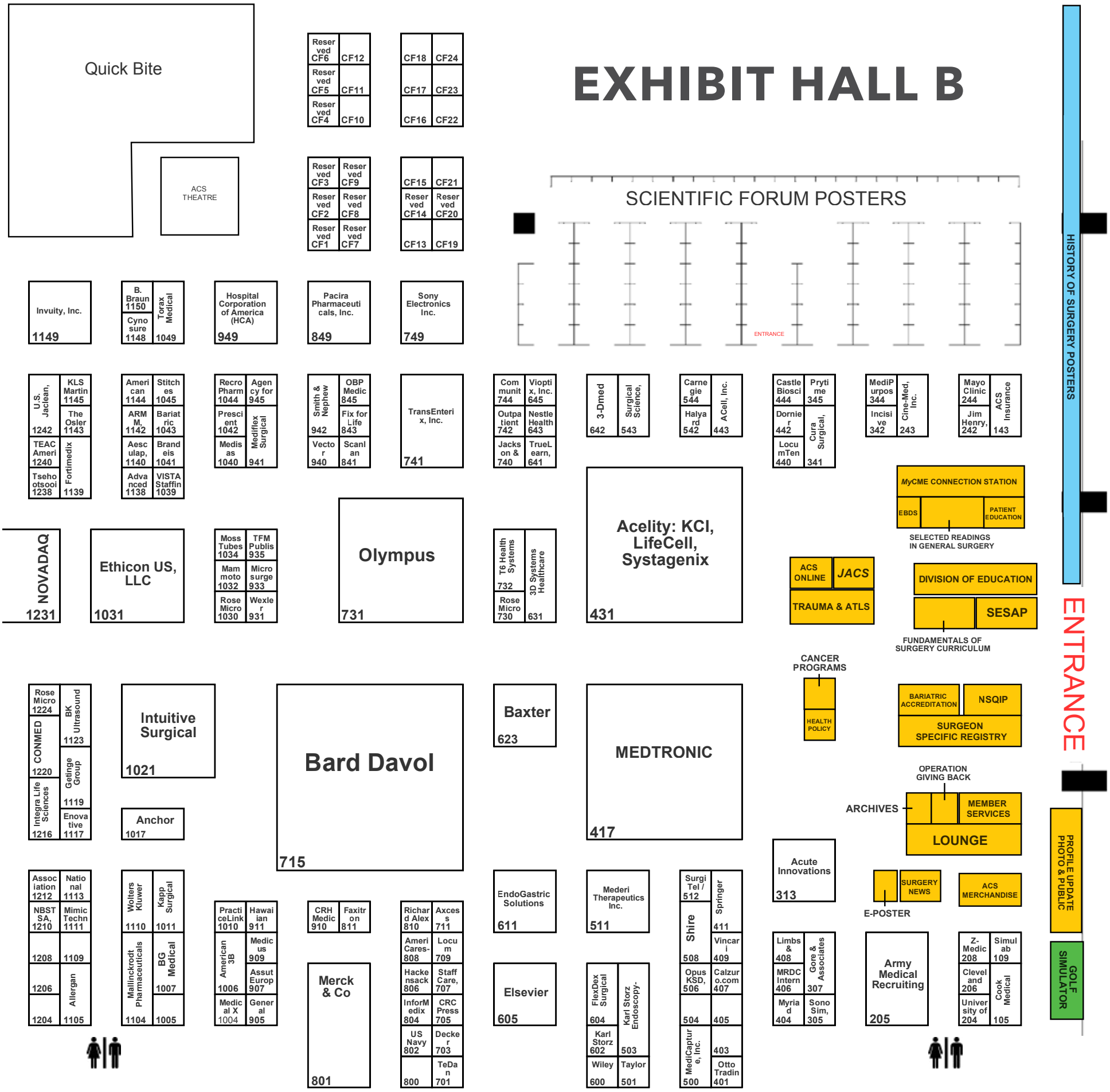

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EXHIBITOR SPOTLIGHT

SCENES FROM CLINICAL CONGRESS 2016

The Past-Presidents of the American College of Surgeons met on Tuesday. **Front row,** left to right (all MD, FACS): Immediate Past-President J. David Richardson; John L. Cameron; Kathryn D. Anderson; LaSalle D. Leffall, Jr.; Andrew L. Warshaw. **Back row:** Gerald B. Healy; Patricia J. Numann; R. Scott Jones; LaMar S. McGinnis, Jr.; L. D. Britt; A. Brent Eastman; Carlos A. Pellegrini.

Deborah A. Kuhls, MD, FACS (center), received the 2016 National Safety Council (NSC) Surgeons' Award for Service to Safety on Monday at the annual Committee on Trauma (COT) dinner. The award reads: "For her persistent, patient, passionate, and effective leadership of the Injury Prevention and Control programs at the American College of Surgeons Committee on Trauma." Presenting the award to Dr. Kuhls were **Raul Coimbra,** MD, PhD, FACS, President, American Association for the Surgery of Trauma, and Past Vice-Chair, COT (left), and **Ronald M. Stewart,** MD, FACS, Chair, COT.

At Clinical Congress 2016, the Scientific Forum Committee reviewed and chose eight posters to be displayed. The Posters of Exceptional Merit will be on display through Wednesday in the Exhibit Hall. **Dani Odette Gonzalez,** MD (second from left), was awarded the Best Scientific Poster of Exceptional Merit Ribbon by the Scientific Forum Committee, including (from left) **Paula M. Termuhlen,** MD, FACS, member; **Dennis P. Orgill,** MD, PhD, FACS, Vice-Chair; and **Mary T. Hawn,** MD, FACS, Chair, Scientific Forum Committee.

Recipients of the American College of Surgeons Distinguished Service Award gathered for their annual luncheon at the Marriott Marquis Washington, DC, Hotel. **Front row,** left to right (all MD, FACS): Mary H. McGrath; LaMar S. McGinnis, Jr.; Amilu Stewart; Murray F. Brennan; and Jack W. McAninch. **Back row:** F. Dean Griffen; John A. Weigelt; David B. Hoyt; Patricia J. Numann; J. Wayne Meredith; Frank G. Opelka; and Richard B. Reiling. Fabrizio Michelassi, MD, FACS, Chair of the ACS Board of Governors, far right.

As part of this year's Clinical Congress Child Care Program, the American College of Surgeons offered a Little Medical School Monday afternoon at the Marriott Marquis Washington, DC, Hotel. Children of Clinical Congress attendees were provided the opportunity to explore the world of medicine, science, and health in an engaging and fun environment. Each child who participated in this optional program received a disposable white physician's coat, organ sticker set, surgical kit, and a graduate diploma.

Practicing surgeons and residents were recognized at Clinical Congress 2016 for their contributions to advancing the art and science of surgery. Recipients honored with the Scientific Forum Excellence in Research Awards included the following (from left): Elizabeth J. Lilley, MD, MPH; Mitchell R. Dyer, MD; Alicia E. Snider, MD; Vanagh C. Nikolian, MD; Marina Ibrahim, MD, CM, MSc; David L. Colen, MD; Rebecca Scully, MD; Matthew A. Hornick, MD; Mary T. Hawn, MD, FACS, Chair, Scientific Forum Committee; Doreen O. Jackson, MD, CAPT USAF; Christy E. Cauley, MD; Scott Dolejs, MD; Dani Odette Gonzalez, MD; Jeffrey A. Pearl, MD; Dana Schwartz, MD; Yehonatan Nevo, MD; and Jared R. Gallaher, MD, MPH.

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HOW MUCH ARE ANASTOMOTIC LEAKS COSTING YOU?

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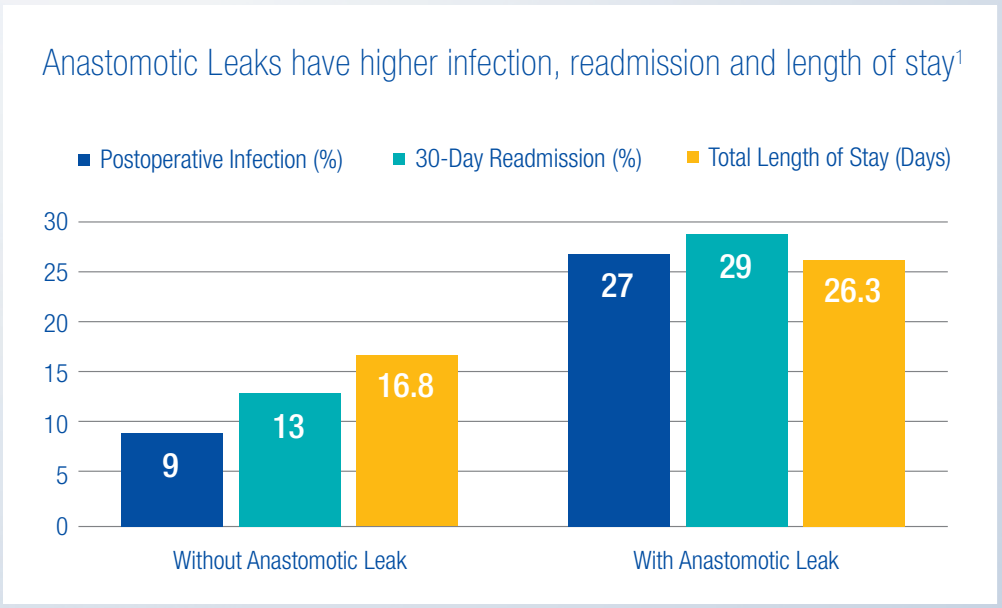

Anastomotic leaks have devastating implications:

- Doubles length of hospital stay[3] and increases cost of $28,600 per patient on average[2]
- Significantly greater chances of wound infection and increased mortality rates of up to 32%[2]

Intra-Operative Endoscopy (IOE) supports better clinical outcomes:[4]

- Allowed the reduction of potential leak rate by 91.8% compared to no testing[4]
- Reduced anastomosis related morbidity from the expected 3.2% to 1.3%[4]

Clinical References:

1. Hammond, J., Lim, S., Wan, Y., Gao, X., & Patkar, A. (2014). *Journal of Gastrointestinal Surgery*, 18(6), 1176-1185.
2. Zhao Y, Encinosa W. The Costs of End-of-Life Hospitalizations, *2007: Statistical Brief #81*. www.hcup-us.ahrq.gov.
3. Britton, Julian, 5 Gastrointestinal tract and abdomen, 29 Intestinal anastomosis, *ACS Surgery*, Dale DC; Federman DD, Eds, New York 2000.
4. Haddad A, Tapazoglou N, Singh K, Averbach A. Role of Intra-Operative Esophagogastroenteroscopy in Minimizing Gastrojejunostomy-Related Morbidity: Experience with 2,311 Laparoscopic Gastric Bypasses with Linear Stapler Anastomosis. *Obesity Surgery*. 2012;22(12):1928-1933

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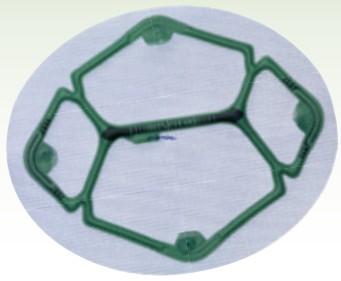

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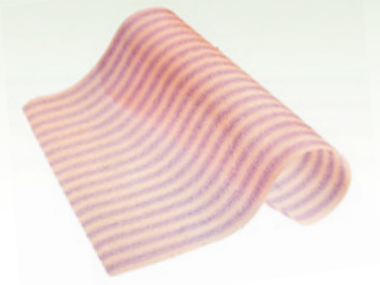

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Monday, 10/17

1:00 PM
J. SCOTT ROTH, MD, FACS
Economic Considerations in AWR: Optimizing Outcomes with BARD's Portfolio and Supporting Clinical Evidence

2:00 PM
JOHN P. FISCHER, MD
AWR Techniques and Principles for Reliable Results

Tuesday, 10/18

11:15 AM
DAVID IANNITTI, MD, FACS
Surgical Techniques and New Clinical Data for an Antibiotic-Coated Graft in AWR

12:15 PM
THOMAS SWOPE, MD, FACS
The Robot for Hernia Repair

Wednesday, 10/19

11:30 AM
MICHAEL ROSEN, MD, FACS
Using the AHS-QC to Add Value to Your Hernia Practice

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